Finding Correlations Between Asthma Exacerbation, Physiological Measurements and Environmental Factors (SCH Asthma)

March 5th, 2021

NCT ID Not yet assignment

North Carolina State University
ADULT CONSENT FORM for RESEARCH

Title of Study: Finding Correlations between Asthma Exacerbation, Physiological Measurements and Environmental Factors **(eIRB# 16598)**
Principal Investigator: Edgar Lobaton, PhD (edgar.lobaton@ncsu.edu and 919-515-5151)
Funding Sources: National Science Foundation and NCSU Center for Human Health and the Environment

What are some general things you should know about research studies?
You are being asked to take part in a research study. Your participation in this study is voluntary. You have the right to be a part of this study, to choose not to participate and to stop participating at any time without penalty. The purpose of this research study is to gain a better understanding of when individuals with asthma experience exacerbation. This will help us study the feasibility of a system that may notify individuals when they are at risk of such reaction. We will do this through the use of wearable and portable devices that will monitor your physical state, and by surveys and interviews about your experience with the system and how you manage your asthma. However, note that we will not be providing any notifications to you as part of this study, but this information will help the researchers toward the development of new techniques for detecting, predicting and preventing asthma exacerbation.

You are not guaranteed any personal benefits from being in this study. Research studies also may pose risks to those who participate. You may want to participate in this research because of the insights about your asthma management. You may not want to participate in this research because you may experience some discomfort wearing and using the devices.

In this form you will find specific details about the research in which you are being asked to participate. If you do not understand something in this form it is your right to ask the researcher for clarification or more information. A copy of this consent form will be provided to you. If at any time you have questions about your participation, do not hesitate to contact the researcher(s) named above or the NC State IRB office (contact information is noted below).

What is the purpose of this study?
The purpose of the study is to determine if it is possible to capture asthma-related physical signs by wearable (e.g., heart rate monitors and activity trackers) and medical (e.g., spirometers) devices in real-world conditions.

Are you eligible to be a participant in this study?
There will be approximately 20 participants in this study.

In order to be a participant in this study you should be 18 years old and be diagnosed with persistent asthma (as characterized in your UNC health record) that is poorly controlled.

You cannot participate in this study if you have any other lung disease other than asthma, take oral steroids every day to control your asthma, need asthma rescue medication multiple times a day, have not experienced wheezing during a lung function test, don't have wireless internet access at home, or you don't feel comfortable with operating the multiple devices including the iOS device provided by the investigators. **The iOS device can only be used for the purposes of this study (i.e., it cannot be used to make calls, play games, etc.).** The iOS device will be restricted by enabling Parental Control Settings accessible only to the researchers.

Your participation may be terminated by the investigator without your consent if you do not follow the guidelines for the study, including using the devices as instructed or participating in the weekly surveys, and interviews at the end of first week, the first month and third month. Also, the monthly renewal for the

participation of the study (up to 4 months) will be decided by the investigators on a month-by-month basis given that you also agree to continue in the study.

What do some of these terms below mean?

Throughout this consent form there are some repeated words or phrases being used that you might not be familiar with and you may ask the researcher for any additional clarification.

- **Environmental Sensor:** It is a device that measures air quality by monitoring particulate matter and other pollutants in the air, humidity and temperature.
- **Spirometer:** It is a medical device that captures how well your lungs function by measuring how much and how quickly you inhale and exhale air.
- **Prototype Device:** It is a device made up of commercially available components that are used as intended for this type of application. In our study, we will use prototype wrist and chest devices developed by the researchers at NCSU.
- **Identifiable information/data**: This refers to any information about you such as your name, e-mail, phone number, or other details that might make your identity easy for the researcher to know.
- **De-identified information/data**: This was once identifiable information that has been recorded by the researcher in a way that your identity is no longer directly on the information. This means that the researcher has a list with your code and real name that they can use to link to your information, but your name and other personally identifiable information, like your email, is not on the information.

What will happen if you take part in the study?

If you agree to participate in this study, you will be asked to do the following:

(1) To participate in a two hour-long initial session at the NC State Park Scholars Children's Specialty Clinic where you will participate in an interview, answer online surveys, and be shown how to use the devices for this study. You will practice donning and doffing the devices. When putting on the chest device, you will have to lift your shirt in a private room. A research assistant will illustrate how to don the device. The assistant will ask for permission to touch you when ensuring that the device is properly placed.

(2) To wear a wrist sensor device for at least 8 hours each day, a ring device every night, and a chest device for at least 4 hours three times a week (i.e., a minimum of 12 hours a week). The devices need to be kept within 5 meters (about 16 feet) from an iOS device that will be provided to you. Once turned on, the appropriate apps should be started for recording using a provided iOS device. The data will be transferred from the iOS device and the devices to a secured and password-protected server in the cloud. Instructions will be provided in the form of online videos after the use of the devices is demonstrated in-person. You should not use the chest device while at school to avoid distractions. The environmental sensor should be set up at home for continuous monitoring of air quality.

(3) To capture cough sounds while sleeping using the provided iOS device.

(4) To take measurements from a spirometer and record forced coughs at the end of every day, and answer survey questions online about asthma management weekly. Reminders will be sent to you over e-mail with the link to survey using our secured Qualtrics software. You can complete the surveys either using your phone or a personal computer.

(5) To attach an accessory to your inhaler which tracks the use of the inhaler. The tracker is an accessory to the inhaler that records data about its use. It will be used as directed, it is commercially available and does not impede the effectiveness or use of the inhaler.

(6) To participate in weekly 10-minute virtual meetings with the investigators to check the status of the devices and participate in 20-minute virtual interviews after one-week, one-month and three-months of completion of the study.

Most of the components are devices commercially available, and they will keep track of your levels of activity and physical state. Instructions for the use of all devices will be provided in the form of online videos after the

use of the devices is demonstrated in-person. You will also receive a document with details on the privacy for each device. We will also make use of a prototype device developed at NCSU that consists of a chest and a wrist device, which you may be asked to wear during the study. The form factor will be similar to that of the commercially available counterparts. This prototype platform is made up of commercially available components that are used as intended for this type of application. These devices have been tested by the investigators in prior studies.

All virtual interviews (as well as the interview in the initial session) will be digitally audio-recorded and the staff member will also take notes. All identifiable information, including names, will be removed from audio files and staff notes, and the audio files will be deleted after transcription is done.

Throughout the time you are using the devices and iOS device, the applications on the iOS device will have visualizations that will show you information such as: your use of the inhaler through the inhaler tracker app. The spirometer app is designed by our partner VitalFlo (https://www.vitalflohealth.com/) and it will not display any results after being used. VitalFlo is providing the framework for us to collect the data from the different devices into a database online for further analysis by our research team. None of this information should be used for medical purposes. The parental control will be enabled in the iOS device so no new apps can be installed. The iOS device cannot be used for any other purpose than this study.

You will follow your normal asthma treatment plan while using the devices. The use of these devices will not affect your treatment, it will only track your use of medications and physical state. The total amount of time that you will be participating in this study is up to four months.

If you get sick during the study (e.g., with a cold, flu or COVID-19), we encourage you to continue with the study. Getting measurements while in this condition will help us identify the effect of these diseases on your respiratory condition. You have the option to pause the study if you do not feel comfortable proceeding by contacting the principal investigator.

If any of the devices are stolen, lost or damaged during the study please notify the investigators immediately. Damaged devices should be returned to the investigators. You are not responsible for any costs if this happens.

Recording

If you want to participate in this research, you must agree to be audio recorded. If you do not agree to be audio recorded, you cannot participate in this research. There will be recording associated with cough sounds and recordings associated with the participants interviews. You will be ask to record forced coughs daily in a quiet area for a few seconds, and audio attributes (e.g., the frequency content of a particular audio interval) will be captured during your sleep using the iOS device. The sleep recordings will only extract attributes from the audio from which we cannot recover speech. Since the sleep recordings could capture some audio attributes from other people in the same room as you, you are required to inform anyone that may be unintentionally recorded (e.g., a roommate) by sharing the provided "Info Sheet for Third Parties." This audio data will be used by our researchers to identify patterns than can predict asthma exacerbation. The audio recordings in the interviews will be used for transcription. Identifiers will be removed from the transcripts and audio recordings will be deleted after transcription. You will not have access to any of these recordings.

Location information

We will request the zip code where you live in order to be able to pull local weather information. Any location information will be discarded once the corresponding weather data is recovered.

Other options

Instead of participating in this research, there are alternative procedures and courses of treatment available to you. These include consulting with your primary care physician and asthma specialists about alternative ways to monitor your asthma.

Risks and benefits

These study procedures have been determined to be minimal risk, but you may perceive risk in the following ways:

- The risks associated with the initial session include: You will need to lift your shirt to place the chest device which may cause some embarrassment. You are encouraged to let us know if this is the case. We will stop the session if you request us to stop.
- The risks associated with using the devices and sensors include: Some of your private behavior may be captured by the sensors when you are using the sensors in an unsupervised setting. For example, they capture how much you move which can be associated with levels of activity. However, we will show you how to turn off the devices, and you can remove them when needed. Specific information about behavior may be hard to identify from the sensing modalities. Although minimal, the devices used throughout the study could cause some skin irritation and/or discomfort (e.g., the electrodes from the prototype chest patch). Prior to the electrode application, the skin will be treated with alcohol and a cleansing solution. If needed, the skin will be shaved in the area where the electrodes are attached. You should not participate if your skin is highly sensitive to electrode adhesive or gel. There is less than 1% chance of rash or blisters, but if they occur you can apply a 1% topical hydrocortisone cream to the area. Also, this discomfort could cause distraction when worn. You are encouraged to notify the principal investigators and stop their use if any irritation, discomfort, or distraction is experienced. The chest device may cause some minor discomfort when donning due to the need for attaching electrodes to the chest area.
- The risks associated with the accessory attached to the inhaler, wrist device, chest device, ring device, the spirometer and the audio recordings include: They capture medically relevant information via their apps, which can be considered private. We anticipate no risks associated with the medical treatment of the participants, as we don't expect any of the devices to affect it in any way.
- Most of the devices will store data directly to the iOS device, which will handled security using the iOS encryption. The Smartwatch is the only device that will store data locally, which will be transferred and deleted from the device every evening. If the device is lost some of this information could remain in this device. However, there will not be any identifiable information present.
- The Hailie inhaler tracker (a product by Adherium) will collect data through its app about the inhaler use. This data will be uploaded to the Adherium's portal and accessed through the Apple Health framework. Adherium will have access to this data, which we plan to release to the scientific community. In order to maintain privacy, the device will be registered using a subject ID without any identifiers. You will have to agree to the privacy policies of the company. Details on the privacy Policy for this device can be found in: https://www.hailie.com/pages/privacy-policy
- The risks associated with completing the surveys and interviews include the recording of medically relevant information in both the surveys and interviews, which can be considered private.
- The risks associated with perception from others: The wrist device and chest device are the only devices that may be observed throughout the day. The chest device is the only one that may raise some questions. However, this device should not be very noticeable since it will be worn under clothes. The other devices will be used at the end of the day so it should be very unlikely that questions arise about them.
- The risks associated with behavior change: The use of these devices and/or the measurements may affect your behavior (e.g., by making you more self-conscious about the use of your medication which may change their regular use). This may also cause some psychological stress. Remember that these measurements may not be 100% reliable since they are not taken under the supervision of a medical

practitioner. If you have any questions or concerns please reach out to your healthcare provider. You are encouraged to stop using the devices if you experience any stress.
- The monitoring of air quality could identify risks associated with exposures to pollutants.

These risks are mitigated by:

- As mentioned above, we will mitigate any issue with the devices by encouraging you to stop using the devices when needed and making the investigators aware of the issue.
- Minor distractions and changes in behaviors caused by the use of the devices is expected to lessen over time as you become less self-aware about their use.
- In order to mitigate any possible stigma with the use of the devices we will make sure you are aware of the value of this study and what the devices do, and how you are contributing to the scientific community by participating.
- We will store the medical information in the iOS device (secured using a pin / passcode) without any identifiers. All data (including surveys and interviews) will be stored in password-protected computers and servers.
- If respiratory distress which is not been managed is discovered, then you will be referred to your medical doctor. If air pollutants are discovered in the air, the research team will first verify that this is not due to a device malfunction, and then you will be referred to a document indicating how to improving air quality. If no steps are taken by the guardians within a timely manner then these conditions will be reported to social services on the basis of neglect.

As a direct benefit, you may gain a better understanding and awareness of your health patterns associated with your asthma control. The data that you provide will help us develop methodologies for early detection, prediction and prevention of asthma exacerbation.

Right to withdraw your participation

You can stop participating in this study at any time for any reason. In order to stop your participation, please contact the principal investigator, Dr. Edgar Lobaton, at edgar.lobaton@ncsu.edu and 919-515-5151. If you choose to withdraw your consent and stop participating, please stop using any of the devices and return all devices to the investigator. If you choose to withdraw your consent and to stop participating in this research, you can expect that the researcher(s) will redact your data from their data set, securely destroy your data, and prevent future uses of your data for research purposes wherever possible. This is possible in some, but not all, cases.

Confidentiality, personal privacy, and data management

Trust is the foundation of the participant/researcher relationship. Much of that principle of trust is tied to keeping your information private and in the manner that we have described to you in this form. The information that you share with us will be held in confidence to the fullest extent allowed by law.

Protecting your privacy as related to this research is of utmost importance to us. There are very rare circumstances related to confidentiality where we may have to share information about you. Your information collected in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA or NSF) for purposes such as quality control or safety. In other cases, we must report instances in which imminent harm could come to you or others.

How we manage, protect, and share your data are the principal ways that we protect your personal privacy. Data that will be shared with others about you will be de-identified.

De-identified. De-identified data is information that at one time could directly identify you, but that we will record so that your identity is separated from the data. We will have a master list with your code

and real name that we can use to link to your data. When the research concludes, there will be no way your real identity will be linked to the data we publish.

Future use of your research data

To help maximize the benefits of your participation in this project, by further contributing to science and our community, your de-identified information will be stored for future research and may be shared with other people without additional consent from you.

Compensation

For participating in this study, you will receive $250 per month of data collection completed. If you complete all four months of data collection, compensation will be $1000. The administrative office at NCSU will require a social security number in order to process the payments. However, this information will not be part of our study records. If these payments exceed $600 in a given calendar year, the Internal Revenue Service (IRS) requires the reporting of this income on a Form 1099. You should consult with your own tax advisor regarding these reporting requirements, and any other state and foreign (if applicable) requirements.

If you withdraw from the study prior to its completion, you will receive only partial compensation proportional to the number of weeks completed within a month (each week is compensated at $62.50). You will not be compensated if you do not use the devices correctly. In this case, you will not be eligible to continue in the study.

Emergency medical treatment

If you are hurt or injured during the study session(s) with the researcher, they will call 911 for necessary care. If you are hurt or need medical care while using any of the study devices, please call 911 or your medical provider. There is no provision for compensation or free medical care for you if you are injured as a result of this study.

What if you are a client of the UNC Children's Clinic?

Your participating in this study is not a requirement nor expectation and your participation, or lack thereof, will not affect your care at the UNC Children's Clinic.

Sponsorship and funding

This research is funded by the National Science Foundation (NSF) and North Carolina State University (NCSU). This means that the sponsors are paying the research team for completing the research. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study. If you would like more information, please ask the researcher listed in the first page of this form about the funding and sponsorship.

What if you have questions about this study?

If you have questions at any time about the study itself or the procedures implemented in this study, you may contact the researcher, Dr. Edgar Lobaton, at 2062 Engineering Building II (on Centennial Campus at NCSU), or 919-515-5151.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include any information that can directly identify you but it will include a summary of this study's results within a year after the study has completed. You can search the clinical trials website at any time to review this study's results once they are posted.

What if you have questions about your rights as a research participant?

If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact the NC State IRB (Institutional

Review Board) office. An IRB office helps participants if they have any issues regarding research activities. You can contact the NC State IRB office via email at irb-director@ncsu.edu or via phone at (919) 515-8754.

You can also find out more information about research, why you would or would not want to be a research participant, questions to ask as a research participant, and more information about your rights by going to this website: http://go.ncsu.edu/research-participant

Consent to participate

By signing this consent form, I am affirming that I have read and understand the above information. All of the questions that I had about this research have been answered. I have chosen to participate in this study with the understanding that I may stop participating at any time without penalty or loss of benefits to which I am otherwise entitled. I am aware that I may revoke my consent at any time.

Participant's printed name _____

Participant's signature _____ **Date** _____

Investigator's printed name _____

Investigator's signature _____ **Date** _____